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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/725,890  
Filing Date: December 02, 2003  
Appellant(s): WALAK, STEVEN E.

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J. Scot Wickhem  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 9-5-2008 appealing from the Office action mailed 1-31-2008.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is substantially correct with the exception being that claim 62, not 52, stands finally rejected under Ren and Viera in view of Rooney.

**(4) Status of Amendments After Final**

No amendment after final has been filed.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

6,045,547	Ren et al	4-2000
6,039,699	Vierra	3-2000
6,306,105	Rooney et al	10-2001
WO 99/58184 A1	O'Brien	11-1999

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-9, 11, 13, 15, 16, 18, 19-21 25-26, 57, 59, 61, 63-64, 66-68, and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ren et al (US 6,045,547), and further in view of Viera (US 6,039,699).

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a. Regarding claim 1, Ren et al teaches a catheter shaft with an inner and outer layer with varying stiffness along the length of the catheter. Specifically taught by Ren et al is, "One catheter tube section has a first, inner layer formed of a flexible material and a second, outer layer formed of a stiffer material." (Abstract). Also taught is, "The outer tube can have a region of substantially constant wall thickness followed distally by a taper which terminates, leaving the inner tube with no outer layer." (Col. 2, lines 17-19) While Ren et al substantially discloses the apparatus as claimed, it does not disclose that both portions should be made of metal. Viera teaches a multi-layer guidewire where each the inner and outer layers are made of metal. "The first material may exhibit superelastic properties and may include an alloy having nickel and titanium. The second material may include stainless steel." (Col. 1 lines 52-55) Those versed in the art would have reasonably recognized and appreciated that guidewires and catheters perform nearly the same function, with the exception that guidewires often do not have lumens. Both devices are designed to be flexible and thin such that they can navigate and pass through body cavities, ducts or vessels. It would be therefore be obvious to one of ordinary skill in the art to make the catheter of Ren et al using the materials suggested by Viera, in this case metallic inner and outer layers. Referral to the **MPEP section 2113** is made, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process

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claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.”

b. Regarding claim 2, Ren et al teaches, “The outer tube can have a region of substantially constant wall thickness followed distally by a taper which terminates, leaving the inner tube with no outer layer.” (Col. 2 lines 17-19) Also see figure 1.

c. Regarding claims 3-4, Ren et al teaches, “...decreasing the thickness of the outer layer with increasing distal position. The thickness of the outer layer can be tapered down over several inches...” (Col. 1 lines 66-67 to Col. 2 lines 1-2) It is apparent from this citation that the outer layer covers a portion of the inner layer in the proximal region.

d. Regarding claims 5, 22, and 70, Ren et al teaches, “Referring now to FIG. 2, a second catheter tube section 42 is illustrated, joined distally at 44 to first section inner layer 34. Second catheter tube section 42 includes an inner layer or tube 46 and an outer layer or tube 48.” (Col. 4, lines 4-7), furthermore there is an alternative embodiment where “A smooth appearance near the junction of two joined tube sections is provided in one embodiment by abutting and bonding the tubes rather than overlapping them.” (Col. 4, lines 20-23) Visualizing the alternative embodiment, it is apparent that moving distally from the proximal region of the abutted assembled tubes, a region with an outer layer would be followed by a region with no outer layer, followed immediately by a region with a second outer layer. As such the ‘assembled’ product of two abutted tubes of Ren

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et al would be structurally indistinguishable from a medical device in which a second segment of the outer layer were allowed to remain upon the inner layer of a medical device.

e. Regarding claims 6 and 7, Ren et al teaches, “One method uses an extruder having a co-extrusion head capable of...” (Col. 4 lines 62-63, emphasis added) If the catheter was produced by co-extrusion or co-drawing the products would be structurally indistinguishable from that of the current application, as such both co-extrusion and co-drawing are taken to be anticipated by Ren et al.

f. Regarding claim 8, Ren et al teaches, “The outer tube can have a region of substantially constant wall thickness followed distally by a taper which terminates, leaving the inner tube with no outer layer.” (Col. 2, lines 17-19)

g. Regarding claims 9 and 10, Reference to **MPEP section 2113** is again made as grinding away or etching the outer metallic layer to expose the inner metallic layer would result in an apparatus that is structurally indistinguishable from Ren et al.

h. Regarding claims 11 and 13, While Ren et al substantially discloses the apparatus as claimed, it does not disclose which metal the inner portion is made of. Viera teaches, “...corewire formed from a material exhibiting superelastic properties, such as a nickel-titanium or Nitinol alloy for example.” (Abstract) It is art recognized and appreciated that nickel-titanium alloy and super-elastic nickel-titanium alloy are used in both catheters and guidewires when a high-flexibility but strong metal is desired. As such it would have been obvious to one of

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ordinary skill in the art at the time the invention was made to form the inner layer of the catheter of Ren et al with nickel-titanium alloy or super-elastic nickel-titanium alloy as taught by Viera due to the alloys ability to withstand large amounts of deformation with a high degree flexibility.

i. Regarding claim 15, Ren et al teaches, "FIG. 1 illustrates a first catheter tube section 20 having a proximal region 22, a distal region 24, and a lumen 40 therethrough." (Col. 3 lines 3-5)

j. Regarding claim 16, While Ren et al substantially discloses the apparatus as claimed, it does not disclose what metal the outer portion is made of. Viera teaches, "The second material may include stainless steel." (Col. 1 lines 54-55) It is art recognized and appreciated that stainless steel is used in both catheters and guidewires as an outer rigid layer that covers a more flexible interior layer. As such it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ren et al to utilize stainless steel as the rigid outer layer as taught by Viera as stainless steel is both more rigid than most other flexible metals and corrosion resistant.

k. Regarding claim 18, it is apparent that Ren et al specifically teaches a catheter, "A multi-layer catheter tube..." (Abstract)

l. Regarding claims 19 and 25, Ren et al suggests a guide catheter via, "Guide catheters are often used as conduits, to guide..." (Col. 1, lines 17-18)

m. Regarding claims 20 and 21, While Ren et al substantially discloses the apparatus as claimed, it does not disclose grinding the inner layer to provide a



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reduced outer diameter on the inner portion (claim 20), or a taper on the inner portion (claim 21). Viera teaches, "Corewire 320 further tapers from segment 326 along a segment 328 to distal segment 330. Segments 324, 326, and 328 may be formed to any suitable length and diameter using a suitable centerless grinding technique, for example." (Col. 2 lines 62-65) The taper and inner layer radius differences would not be easily formed by the co-extrusion method addressed by Ren et al and in some cases, depending upon the region of the body the catheter is intended to go through, a changing inner layer radius is desirable as opposed to the one taught by Ren et al. Therefore it would be obvious to one of ordinary skill in the art at the time the invention was made to grind the metallic inner portion of Ren et al as taught by Viera to provide a different segment length or radius and to have a taper between regions of different radii because it would provide a method to create multiple segments with varying lengths and outer radii to better customize catheter properties such as flexibility in specific regions of the catheter.

n. Regarding claims 26 and 27, it is well known within the art that modulus of elasticity and torsional rigidity are properties that represent stiffness. An object having a higher modulus of elasticity relative to another with similar shape, it would inherently mean that the object is more rigid. Torsional rigidity is similar, if an object had higher torsional rigidity, it would inherently be more rigid relative to another object of similar shape. It would thus have been obvious to one of ordinary skill in the art to have the modulus of elasticity and torsional rigidity of the

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inner metallic portion be lower than that of the outer metallic portion, because modulus of elasticity and torsional rigidity are measures of stiffness and Ren et al teaches having a stiffer outer layer compared to inner layer. (See citation in claim 1 above)

o. Regarding independent claims 57 and 73, Ren et al teaches, "The outer layer tapers distally, having decreasing layer thickness with increasing distal position. The decreasing wall thickness provides a decreasing stiffness contribution which imparts increasing flexibility to the catheter portions having a smaller outer layer." (Abstract). Ren et al also teaches why these properties are desirable, "Advancing a catheter along the above described path requires pushability, torqueability and flexibility in differing degrees in different regions of the catheter shaft. In particular, the proximal region of the catheter shaft will ultimately lie within the femoral artery, where flexibility is not as important as the pushability of the torqueability required to maneuver the more distal regions of the catheter disposed within the coronary arteries. (Col.1, lines 27-34) Combined with the reasons for rejecting claim 1 in paragraph 3a above, it would have been obvious to one of ordinary skill in the art to make a catheter with a lumen and inner and outer layers made of different metals with the distal region of the inner layer exposed to provide a higher level of flexibility to the distal region relative to the proximal region and a higher level of stiffness to the proximal region relative to the distal region, in order to create a catheter with the art recognized desirable

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properties of pushability and torqueability in the proximal region of a catheter and maneuverability in the distal region of the catheter.

p. Claims 59 and 61 are rejected for the same reasons as established in claims 11, 13, 26 and 27 above.

q. Claim 63 is rejected for the same reasons as established in claims 15, 26 and 27 above.

r. Claim 64 is rejected for the same reasons as established in claims 16, 26 and 27 above.

s. Claim 66 is rejected for the same reasons as established in claims 18, 26 and 27 above.

t. Claim 67 is rejected for the same reasons as established in claims 18 and 25-27.

u. Claim 68 is rejected for the same reasons as established in claims 20, 21, 26 and 27 above.

2. Claims 12, 17, 60, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over references Ren et al (US 6,045,547) and Viera (US 6,039,699) as applied to claims 1 and 57 above, and further in view of O'Brien et al (WO 99/58184).

v. Regarding claims 12 and 60, While Ren et al substantially discloses the apparatus as claimed, it does not disclose making the metallic inner portion of beta titanium. O'Brien et al however, which is drawn to a stent deploying apparatus teaches beta-titanium as a composite to form the medical device. Specifically taught is "...In the over-the-wire catheter of the present invention, the

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inner tube 134 or outer tube 136 (or both) is formed of a beta-titanium material.

The beta-titanium material has a relatively low modulus of elasticity and pseudoelastic characteristics for tracking through..." (Page 15 lines 17-20). It would thus have been obvious to one of ordinary skill in the art at the time the invention was made to form the inner metallic tube of Ren et al and Viera from beta-titanium as taught by O'Brien et al because beta-titanium's properties paralleling those taught as desirable by Ren et al and Viera, the property of a low modulus of elasticity particularly.

w. Claims 17 and 65 are rejected for the same reasons as stipulated in claims 12 and 16 above.

3. Claims 14 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ren et al (US 6,045,547) and Viera (US 6,039,699) as applied to claims 1 and 57 above, and further in view of Rooney et al (US 6,306,105 B1).

x. Regarding claims 14 and 62, While Viera substantially discloses the apparatus as claimed such as super-elastic nickel titanium alloy it does not disclose a linear-elastic nickel-titanium alloy inner metallic layer. Rooney et al however teaches a guide wire similar to that taught by Viera with "...a nickel-titanium core with a stainless steel coil to provide a wire with improved kink resistance and good pushability." (Abstract) and "...core 20 may preferably be formed of a linear-elastic alloy of nickel titanium" (Col. 3 lines 37-39) It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to compose the metallic inner layer of Ren et al and Viera of

a linear-elastic nickel-titanium alloy as taught by Rooney et al in order to provide improved kink resistance and good pushability.

**(10) Response to Argument**

***Claim Rejections - 35 USC § 103***

Claims 1 and 57 are rejected under 35 U.S.C. 103 as being unpatentable over Ren et al (US 6,045,547) in view of Viera (US 6,039,699).

Appellant argues that that substitution of the metallic materials of Ren with the joining methods taught by Ren would not produce the claimed structure. The Examiner disagrees, creating the device of Ren et al with two metal layers as taught by Viera would provide the claimed structure. In the Appeal Brief on page 11, appellant states that the adhesive, welding, brazing or soldering as taught by Viera (Col.4 lines 26-29) would not result in the proper attachment to create a unitary structure. Constructing a composite elongate shaft of metals as claimed does result in a unitary structure. The examiner notes that the present claims are written using product-by-process language. The product as claimed could be made by creating the first metallic layer as a loose tube that is then fit over the second metallic layer and then using the bonding methods of Ren or Viera. Note that Appellant's specification states that suitable attachment techniques to create a unitary structure can include extrusion, adhesive bonding, welding, and soldering (page 8 line 23 to page 9 line 2). Ren et al specifically teaches co-extrusion as the method of forming the device (Col.4 lines 60-64).

Appellant argues that one of ordinary skill in the art would not use the metal/polymer fastening techniques of Ren if using the two metal materials of Viera. However, Ren et al only teaches using a semi-continuous co-extrusion process (Col.4 line 60 to Col.5 line 8) One of ordinary skill in the looking to replicate Ren et al would see the co-extrusion method used to join the first and second layers (at no point in this paragraph are polymers and metals mentioned, only the properties of the desired layers) and would apply a co-extrusion method to the materials being used. In view of Viera, this would result in a metal co-extrusion. One of ordinary skill in the art would recognize that metals and plastics are extruded differently yet both are still capable of being co-extruded as taught by Ren et al.

Appellant further argues that the smoothly tapered end transition as shown with element 31 of Figure 3 of Ren is effectively impossible. This is neither claimed, nor does it inherently flow from the process steps. However, patent 3,422,648 shows a method (such as figures 7 and 8) by which a taper is created on a metallic object. Additionally, patent 5,557,962 shows the extrusion of an elongated, hollow with a moving piece 8 that allows for customization of the outer layer of the extruded tube, such as tapering or geometric shapes.

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

/Bradley J Osinski/

Examiner, Art Unit 3767

Conferees:

/Kevin C. Sirmons/

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TC 3700 TQAS